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BIOETHICS BEYOND THE BIOSPHERE: USING HUMAN SUBJECT MEDICAL RESEARCH TO CHART OUT REGULATION AND LIABILITY FOR HEALTH RISKS IN OUTER SPACE

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Humans may be living in outer space sooner than we think. Because of the elevated potential for detrimental effects to human health in space, ethical standards must be established prior to the widespread formation of human space settlements. This article offers a framework for analyzing the bioethics of humans in space by analogizing the uncertainty in establishing a precautionary and liability framework for health risks in space by using models for medical experimentation on Earth.

An exploration of conventional bioethics principles, international guidelines for medical research, and regulations in the United States will parallel a precautionary framework for ensuring protections for humans during space travel. Past lawsuits brought by human-subject military members and private citizens in medical studies will provide an analogy to potential liability for health-related injuries in space. With many looking to the a future for humans beyond Earth, using this precedent to establish a precautionary and liability-based framework is ultimately a

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necessary step toward ensuring protections and liability for humans in space.

I. THE VAST UNKNOWN: AN ANALOGY BETWEEN MEDICAL HUMAN SUBJECT RESEARCH PROTECTIONS AND THE LIABILITY OF HEALTH RISKS IN SPACE

"Space: the final frontier."[1] These legendary words spoken during the premiere of *Star Trek* in the late 1960s continue to captivate audiences who desire "to go boldly where no man has gone

[1] *Star Trek* (Paramount Pictures Corp. 1967).

before."[2] Enthralled by the idea of human beings traveling and living in outer space, audiences have watched the Starship *Enterprise* venture into the dark depths of the universe for over forty years. Almost a decade before the debut of *Star Trek*, though, the Soviet Union made actual advances toward a future in space by launching the first artificial satellite, *Sputnik*, into Earth's atmosphere on October 4, 1957.[3] Since that day, many have looked to outer space as the future of civilization.

Today, we live in the era after the Space Age, but the spirit behind the Space Race continues to permeate twenty-first century culture.[4] New technologies and the mysteries of the vast expanse of the universe engulf modern society. The Starship *Enterprise*, the intriguing friendliness of E.T., and the intergalactic battles of *Star Wars* continue to captivate audiences of film and literature through modern takes on space exploration, including the 2015 film *The Martian*.[5] Though surrounded by an abundance of fantasy in media, many individuals fail to realize that these fantasies may soon become reality. Many space agencies, companies, and nations have

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[2] *Id.*

[3] Steve Garber, *Sputnik and The Dawn of the Space Age*, NASA HIST. (Oct. 10, 2007), https://history.nasa.gov/sputnik/.

[4] *See* Neil deGrasse Tyson, *Reaching for the Stars: Instead of Counting Smart Bombs, Perhaps We Should Count Smart Scientists.*, NAT. HIST. MAG., Apr. 2003, at 20, 20–21.

[5] *See*, *e.g.*, Stephanie Merry, *The Aliens in "Arrival" Are Stunning. How Do They Compare to Other Film Creatures?*, WASH. POST (Nov. 11, 2016), https://www.washingtonpost.com/entertainment/the-aliens-in-arrival-are-stunning-how-do-they-compare-to-other-film-creatures/2016/11/11/8fa05cf0-a0fe-11e6-8832-23a007c77bb4_story.html?noredirect=on&utm_term=.fd470c7ea53f (comparing the character E.T. to current renditions of extraterrestrial life in film); Brooke Sabin, *Ron Howard on the Importance of Space Travel*, NAT'L GEOGRAPHIC (Nov. 7, 2018), https://www.nationalgeographic.com/travel/features/space-travel-starstuck-ron-howard/ (describing Ron Howard's work on the *Star Wars* series and his prediction for a future in space through exploration as shown in *Star Trek*); Robert Zubrin, *How Scientifically Accurate Is The Martian*?, GUARDIAN (Oct. 6, 2015), https://www.theguardian.com/film/2015/oct/06/how-scientifically-accurate-is-the-martian (noting the significance of the 2015 film, *The Martian*, in being one of the first Mars movies to have a narrative based upon humans exploring the terrain of the Red Planet).

already developed plans to begin colonizing Mars in the next few years.[6]

While many may be eager to begin establishing widespread settlements in space, the unknown beyond the biosphere of Earth presents many questions concerning preventative measures to protect humans in space. Additionally, uncertainties also exists within potential legal liability in space that would allow for recovery from injuries. Similar discussions on protections and liability have occurred within medical research, in which universal bioethical principles guide human subject policies in the United States and internationally.[7] These foundational principles, policies, and cases can provide insight into a potential framework for analyzing health risks in space. This article will explore parallels between space exploration and medical experimentation that exist due to the inherent risks present in both activities. Part II will cover the historical context of space exploration. Part III will connect the present hazards of the space environment to medical experimentation risks and will suggest a legal framework utilizing standard bioethical precautions and established liability standards from human subject research. Part IV will use this precedent to chart out a recommended framework for protections and liabilities for space risks. By evaluating the feasibilities of both precautionary risk management and measures for recovery for injury, an ethical and legal framework for protecting human health in space can be established.

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[6] *See* Remarks at the John F. Kennedy Space Center in Merritt Island, Florida, 1 PUB. PAPERS 497–501 (Apr. 15, 2010), https://www.gpo.gov/fdsys/pkg/PPP-2010-book1/pdf/PPP-2010-book1-doc-pg502-3.pdf; *see also* Mike Wall, *Elon Musk Wants Giant SpaceX Spaceship to Fly People to Mars by 2024*, SPACE.COM (Sept. 29, 2017), https://www.space.com/38313-elon-musk-spacex-fly-people-to-mars-2024.html.

[7] Robert M. Tenery, *Medical Ethics: Medical Etiquette*, 315 JAMA 1291, 1291 (2016).

II. WHERE WE HAVE BEEN: A BRIEF HISTORY OF SPACE EXPLORATION AND PRESENT ISSUES

As some nations plan to colonize Earth's moon and Mars in the next few years,[8] exploration is no longer the only goal of space organizations. Many scientists now view colonization as one of the primary objectives of space travel and the future of the human race.[9] Ideas concerning space colonization are not simply a product of the 21st century, however. In 1869, Edward Everett Hale published a short story of an artificial satellite called "The Brick Moon,"[10] inspiring many others to consider the idea of establishing a colony in the expanse of the universe beyond Earth's atmosphere. As the dream of space travel became a reality during the 20th century, nations drafted the Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space including the Moon and Other Celestial Bodies ("Outer Space Treaty") in 1967.[11] This treaty formed the basis of international space law under the United Nations Office of Outer Space Affairs and continues to govern all activities in outer space.[12]

While support for space exploration has continued since the Space Race, during the past fifteen years, many political leaders have also confirmed their support of space colonization. In 2004,

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[8] Memorandum on Reinvigorating America's Human Space Exploration Program, 2017 DAILY COMP. PRES. DOC. 902 (Dec. 11, 2017), https://www.gpo.gov/fdsys/pkg/DCPD-201700902/pdf/DCPD-201700902.pdf; Sarah Fecht, *The United Arab Emirates Wants to Build a City on Mars*, POP. SCI. (Feb. 14, 2017), https://www.popsci.com/united-arab-emirates-wants-to-build-city-on-mars (noting the desire of the United Arab Emirates to colonize Mars).

[9] *See* Kate Kelland, *Stephen Hawking Urges Space Mission to Save Humanity in 70th Birthday Address*, NAT'L POST (Jan. 8, 2012), http://news.nationalpost.com/2012/01/08/stephen-hawking-urges-be-curious-in-birthday-speech/ (noting that during a birthday speech in 2012, Stephen Hawking said: "I don't think we will survive another thousand years without escaping beyond our fragile planet.").

[10] *See generally* EDWARD EVERETT HALE, THE BRICK MOON AND OTHER STORIES (1899) (introducing the idea of an artificial satellite or space station into orbit).

[11] Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies, Dec. 19, 1966, 610 U.N.T.S. 205.

[12] *See id.*

President George W. Bush challenged NASA to develop a mission to the moon as early as 2015 "with the goal of living and working there for increasingly extended periods of time."[13] Six years later, in 2010, President Barack Obama expanded the idea of space colonization to the planet Mars by affirming that:

> [b]y the mid-2030s, I believe we can send humans to orbit Mars and return them safely to Earth. And a landing on Mars will follow. And I expect to be around to see it . . . .
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> . . . .
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> . . . [The] goal is no longer just a destination to reach. Our goal is the capacity for people to work and learn and operate and live safely beyond the Earth for extended periods of time, ultimately in ways that are more sustainable and even indefinite.[14]

More recently, during President Donald Trump's inaugural address in January 2017, he expressed his support for the future of space exploration in the United States, indicating that "[w]e stand at the birth of a new millennium, ready to unlock the mysteries of space . . . ."[15] In December 2017, President Trump signed an executive order establishing a national policy for the United States to focus on the human exploration of space by returning to the moon and putting Americans on Mars.[16] The directive also called upon the United States to:

> [l]ead an innovative and sustainable program of exploration with commercial and international partners to enable human expansion across the solar system and to bring back to Earth new knowledge and opportunities. Beginning with missions beyond low-Earth orbit, the

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[13] Remarks at the National Aeronautics and Space Administration, 1 PUB. PAPERS 58 (Jan. 14, 2004), https://www.gpo.gov/fdsys/pkg/PPP-2004-book1/pdf/PPP-2004-book1-doc-pg56.pdf.

[14] Remarks at the John F. Kennedy Space Center in Merritt Island, Florida, *supra* note 6, at 500–01.

[15] Inaugural Address, 2017 DAILY COMP. PRES. DOC. 3 (Jan. 20, 2017), https://www.govinfo.gov/content/pkg/DCPD-201700058/pdf/DCPD-201700058.pdf.

[16] Reinvigorating America's Human Space Exploration Program, 82 Fed. Reg. 59,501 (Dec. 14, 2017); *see also* Memorandum on Reinvigorating America's Human Space Exploration Program, *supra* note 8; Michael R. Pence, *Remarks by Vice President Pence at Second Meeting of the National Space Council*, THE WHITE HOUSE, OFF. OF THE VICE PRESIDENT (Feb. 21, 2018), https://www.whitehouse.gov/briefings-statements/remarks-vice-president-pence-second-meeting-national-space-council/.

> United States will lead the return of humans to the Moon for long-term exploration and utilization, followed by human missions to Mars and other destinations.[17]

Subsequently, in a memorandum, Vice President Mike Pence, Chair of the National Space Council, provided a recommendation that the Council "initiate a policy review of the current export licensing regulations affecting commercial space activity."[18] In August 2018, Vice President Pence, with Secretary of Defense James Mattis by his side, confirmed efforts to establish the United States Department of the Space Force by 2020.[19] The idea received some opposition[20] but also received support from government officials[21] and scientific researchers.[22]

It is still unknown whether the Space Force will simply involve remote satellite sensing that already occurs under the United States

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[17] 82 Fed. Reg. 59,501 (Dec. 14, 2017).

[18] Policy Recommendations by Vice President Michael R.Pence on Moon, Mars, and Worlds Beyond, THE WHITE HOUSE, OFF. OF THE VICE PRESIDENT (Feb. 21, 2018), https://www.nasa.gov/sites/default/files/atoms/files/moon_mars_worlds_beyond.pdf. The full title of the memorandum is "Moon, Mars, and Worlds Beyond: Winning the Next Frontier." *See id.*

[19] Vice President Michael R. Pence, Address at The Pentagon on the Future of the U.S. Military in Space, THE WHITE HOUSE, OFF. OF THE VICE PRESIDENT (Aug. 9, 2018), https://www.whitehouse.gov/briefings-statements/remarks-vice-president-pence-future-u-s-military-space/.

[20] *See* Phil Stewart & Susan Heavey, *Going Where No President Has Gone Before, Trump Wants Space Force by 2020*, REUTERS (Aug. 9, 2018), https://www.reuters.com/article/us-usa-military-space/going-where-no-president-has-gone-before-trump-wants-space-force-by-2020-idUSKBN1KU209 (noting that even the Secretary of Defense, Jim Mattis, originally opposed creating a separate military branch for the Space Force).

[21] Sandra Erwin, *Air Force Secretary Affirms Support for Space Force*, SPACE NEWS (Sept. 5, 2018), https://spacenews.com/air-force-secretary-affirms-support-for-space-force/ (noting Secretary of the Air Force, Heather Wilson giving her support for the establishment of a Space Force).

[22] Neil deGrasse Tyson, *Neil deGrasse Tyson on What Space Militarization Means*, MSNBC MORNING JOE (Sept. 12, 2018, 5:45 AM), https://www.msnbc.com/morning-joe/watch/neil-degrasse-tyson-on-what-space-militarization-means-1318568515936?v=raila&. In the interview, astrophysicist Neil deGrasse Tyson provided a historical perspective of the partnerships created between government and scientists in the past. *See id.*

Space Command[23] or will also involve service members working in outer space. Although service members may not initially work directly in space, with a renewed national focus on space exploration and public-private partnerships with commercial space entities, space military operations will likely involve more human-centric functions. It is a question of when, not if, this shift in operations will occur, and the establishment of a Space Force may be the first step toward that goal.

The Space Force may also have an impact upon private space organizations, opening pathways for further commercialization of outer space. Within the private sector, many corporations are planning on sending humans into space in the next few years. SpaceX,[24] for example, was founded with the "ultimate goal of enabling people to live on other planets."[25] SpaceX additionally has targeted 2024 for a manned mission to Mars in order to prepare a base to begin building a "thriving city and eventually a self-sustaining civilization on Mars."[26] In September 2018, SpaceX announced that it had signed the world's first private passenger on a flight set to go around the moon.[27] Additionally, Amazon CEO and founder of Blue Origin, Jeff Bezos, indicated his aspiration for space tourism to be the first step toward "millions of people living and working in space."[28] Virgin Galactic CEO, Richard Branson, is also

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[23] The U.S. Space Command, which is part of the United States Air Force, currently employs more than 30,000 space professionals worldwide and provides support for space capabilities including satellites and surveillance. *Air Force Space Command: About Us*, AIR FORCE SPACE COMMAND, https://www.afspc.af.mil/About-Us/ (last visited Nov. 1, 2018).

[24] *Capabilities & Services*, SPACEX, https://www.spacex.com/about/capabilities (last visited Nov. 1, 2018). SpaceX was founded in 2002 by Elon Musk and designs rockets and spacecraft. *See id.*

[25] *Making History*, SPACEX, https://www.spacex.com/about (last visited Nov. 16, 2018).

[26] *Making Life Multiplanetary*: *Private Lunar Mission*, SPACEX https://www.spacex.com/mars, (last visited Sept. 17, 2018).

[27] *Private Lunar Mission*, SPACEX, https://www.spacex.com/mars (last visited Nov. 13, 2018). On September 13, 2018, SpaceX announced that Yusaku Maezawa, a fashion innovator, will be the company's first private passenger to fly around the moon in 2023. *See id.*

[28] Anita Balakrishnan, *Why Jeff Bezos wants Millions of People to go to Space*, CNBC (Mar. 8, 2017), https://www.cnbc.com/2017/03/07/watch-amazon-

working toward supporting tourism in space.[29] With government and billionaire support, it is likely that both public and private sectors will continue to increase their presence in space.

The implications of a Space Force will likely affect many aspects of society on Earth. Military operations historically have altered history as conquest often precedes property ownership.[30] Similarly, the opening of opportunities for commercial space entities will likely occur as the Space Force paves the way for future settlement. As a result, the establishment of the Space Force will likely accelerate the process of private colonization of space environments. Because outer space is inherently hostile to the health of the human body, however, the ethics and legality of detrimental effects on human health in space must be addressed prior to establishing pathways for permanent human settlements outside of Earth. These effects may first impact members of a Space Force but will inevitably affect other individuals in the future.

III. WHERE WE ARE GOING: USING ANALOGY TO CREATE A BIOETHICAL FRAMEWORK FOR ETHICAL AND LEGAL LIABILITIES FOR HUMAN HEALTH IN SPACE

Because human exploration of space is not yet widespread, many policy and ethical regulations for humans in space have not surfaced to protect individuals from the hazards of the space environment. Traditional bioethical principles concerning human-subject medical research, however, analogize well to space exploration because of the mutual risks involved in both medical experimentation and space travel. Analogizing how these principles

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founder-jeff-bezos-discusses-the-future-of-his-private-spaceflight-company.html.

[29] Christian Davenport, *Richard Branson's Virgin Galactic Just Got Another Step Closer to Flying Tourists to Space*, WASH. POST (May 29, 2018), https://www.washingtonpost.com/news/the-switch/wp/2018/05/29/richard-bransons-virgin-galactic-just-got-another-step-closer-to-flying-tourists-to-space/?noredirect=on&utm_term=.d9b408a44625.

[30] *See generally* NORMAN BENTWICH, THE LAW OF PRIVATE PROPERTY IN WAR, WITH A CHAPTER ON CONQUEST 1–4 (London: Sweet & Maxwell eds., 1907) (detailing a number of historical instances of conquest ranging from the Romans to the Europeans, among others).

apply to the experimental nature of human space exploration can provide a necessary framework for a potential regulatory scheme. Liability mechanisms for medical experimentation can also supply a parallel structure of potential legal repercussions for injury to human space explorers.

A. *Lost in Space: The Common Uncertainty between Medical Experimentation Risks and the Hazards of the Space Environment*

Humans in space will inevitably face numerous health hazards. Consequently, using the existing state of legal issues within medical experimentation on Earth can aid in providing a framework for liability in space. The primary connection between the first humans in space and individuals participating in medical research trials is the uncertainty and inherent risk associated with both. Unfortunately, the ethics and legal liability of medical experimentation has been a regressive study that followed the actions of investigators instead of preceding them.[31] Because human presence in space is not yet widespread, societies have an opportunity to explore ethical and legal questions about the risks of having humans live outside of Earth's orbit prior to the establishment of extraterrestrial settlements. Although the health hazards in space may not involve the intake of a new drug as with many current medical trials[32] or a study for a new surgical procedure,[33] significant parallels can be drawn between space exploration and clinical trial research.

The National Institutes of Health ("NIH") defines a clinical study as involving "research using human volunteers" and notes that such studies are intended to add to medical knowledge.[34] According to the Merriam-Webster Dictionary, "research" is defined as a "careful and diligent search" or "studious inquiry or examination;

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[31] *See infra* text accompanying note 89.

[32] ANN RAVEN, CLINICAL TRIALS: AN INTRODUCTION 5 (CRC Press eds., 2nd ed. 2016) (covering the nature of the process for drug testing with clinical trials).

[33] *See generally* Marco Kawamura Demange & Felipe Fregni, *Limits to Clinical Trials in Surgical Areas*, 66 CLINICS 159, 159–61 (2011).

[34] *Learn About Clinical Trials*, CLINICAL TRIALS.GOV, https://clinicaltrials.gov/ct2/about-studies/learn (last visited Nov. 13, 2018).

especially: investigation or experimentation aimed at the discovery and interpretation of facts . . . ."[35] Similarly, "to explore" is defined as "to investigate, study, or analyze: look into" or "to become familiar with by testing or experimenting."[36] Exploration and research, by definition, are often interchangeable, creating a basis for substantial parallels between health research performed on Earth and the health risks associated with space exploration.

Current space explorers experience a number of physiological dangers.[37] Further efforts to send humans deeper into space and possibly to Mars will increase the possibility of injury. Traveling to Mars for a vacation and discovering extraterrestrial life may seem exciting and adventurous, but space colonization could have detrimental consequences for humanity and the entire universe.

In the process of colonizing, humans will face unfavorable physical and psychological conditions,[38] and the presence of humans in space will inevitably increase the geographical separation of the human race.[39] Terraforming other planets—a proposed concept of transforming a planet's landscape into an Earth-like environment—would also involve strain on human health as space travelers attempt to adapt to the outer space environment.[40] Bone degeneration,[41] vision degradation,[42] fatigue,[43] neurological disorders,[44]

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[35] *Research*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/research (last visited Sept. 26, 2018).

[36] *Explore*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/explore (last visited Sept. 26, 2018).

[37] *See infra* text accompanying notes 41–50.

[38] PETER ECKART, SPACEFLIGHT LIFE SUPPORT AND BIOSPHERICS 39 (James R. Wertz et al. eds., 1996).

[39] F. B. Schick, *Space Law and Communication Satellites*, 16 W. POL. Q. 14, 33 (1963).

[40] Lecture, Cole Miller, Dep't of Astronomy, Univ. of Md., Terraforming and the Future of Humans in Space–Lecture 27: Life in the Universe (2009), http://www.astro.umd.edu/~miller/teaching/astr380f09/lecture27.pdf.

[41] DIRK C. GIBSON, TERRESTRIAL AND EXTRATERRESTRIAL SPACE DANGERS: OUTER SPACE PERILS, ROCKET RISKS AND THE HEALTH CONSEQUENCES OF THE SPACE ENVIRONMENT 207 (2015).

[42] *Id.* at 217.

[43] *Id.* at 83.

[44] *Id.* at 252.

cardiovascular changes,[45] muscle deterioration,[46] digestive problems,[47] immunity suppression,[48] damage from carcinogenic rays and flares,[49] microbial infections,[50] in addition to possibilities of flight accidents,[51] all may contribute to the dangers to humans in space. NASA researchers have categorized these dangers by identifying the mechanisms through which the hazards could occur.[52] Such categories include the microgravity[53] environment and confining spaces that space travelers experience, leading to weakening of bodily systems.[54]

Hostile external environments also present dangers through exposure to extreme conditions.[55] The long distance from Earth produces a risk of not having supplies or ability to treat medical issues.[56] Despite protection through spacesuits and enclosed infrastructure, the human body will gradually deteriorate when exposed to the foreign environments of other planets.[57] During flight and spacewalks, astronauts endure increased amounts of radiation, low gravity, extreme temperatures,[58] and other hazards that threaten

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[45] *Id.* at 241

[46] *Id.* at 284.

[47] *Id.* at 272.

[48] *Id.* at 275.

[49] *Id.* at 304.

[50] *Id.* at 291.

[51] Anna Heiney, *'Forever Remembered' Shares Enduring Lessons of Challenger*, *Columbia*, NASA HIST. (June 27, 2015), https://www.nasa.gov/feature/forever-remembered-shares-enduring-lessons-of-challenger-columbia.

[52] Laura J. Abadie, Charles W. Lloyd & Mark J. Shelmer, *The Human Body in Space*, NASA HUM. RES. PROGRAM (June 11, 2018), https://www.nasa.gov/hrp/bodyinspace.

[53] Microgravity denotes less gravity than on Earth. This equates to $1x10^{-6}$ g, where "g" represents "normal gravity." *See What Is Microgravity?*, NASA (Feb. 13, 2009), https://www.nasa.gov/centers/glenn/shuttlestation/station/microgex.html.

[54] *Id.*

[55] *Id.*

[56] *Id.*

[57] *See* JOEL S. LEVINE & RUDY E. SCHILD, THE HUMAN MISSION TO MARS: COLONIZING THE RED PLANET 361 (2010).

[58] WAYNE LEE, TO RISE FROM EARTH: AN EASY TO UNDERSTAND GUIDE TO SPACEFLIGHT 294 (1995).

human survival.[59] In space colonies, individuals will lose access to basic necessities of life, including water,[60] soil to grow food, and essential levels of sunlight, while potentially facing dangerous wind storms and unpredictable changes in climate.[61] Because humans have not yet traveled beyond low Earth orbit,[62] unknown factors, such as diseases, psychological effects, and possibilities of finding other life, also pose risks to spacefarers. Ultimately, there is much uncertainty about the environment that space-goers will have to endure, in the same way that individuals assume unknown risks within medical research and clinical trials. The unknown risk of both medical experimentation and space exploration provide a basis for using human subject research as a framework for developing protections for humans in space.

B. *Preventative Care: Fundamentals of Human Subject Testing and the Precautionary Framework*

Although uncertainty in the health hazards of the space environment will remain present throughout future missions, traditional bioethical principles can provide insight into potential ethical considerations in outer space based upon currently known dangers in space. For medical experimentation, a variety of principles have established traditional standards to evaluate bioethical issues. International and United States guidelines and regulations have shaped the landscape of bioethics on Earth.[63] Due to the similarity between the risks associated with medical experimentation and the risks that will be endured by humans in space, the current bioethical framework for human subject research should also be applied to humans in space. By analogizing the common bioethical principles utilized on Earth to the inherent health concerns of space exploration, correlations can be made between

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[59] *Id.* at 295.

[60] *Id.* at 290.

[61] ROBERT ZUBRIN, THE CASE FOR MARS: THE PLAN TO SETTLE THE RED PLANET AND WHY WE MUST 129–32 (2011).

[62] Low Earth orbit is the first 100 to 200 miles of space. David Hitt, *What Is an Orbit?*, NASA (July 7, 2010), https://www.nasa.gov/audience/forstudents/5-8/features/nasa-knows/what-is-orbit-58.html.

[63] *See infra* notes 70, 74, 77, 94 and accompanying text.

human subjects on Earth and human travelers in space. For example, in a potential framework, exposure of humans to the hostile space environment can correlate with medical experimentation. Spacefarers will have a parallel with human subjects in medical trials. Scientists and researchers will correspond to the overseeing space organizations, agencies, or companies for space missions. Through these analogies, bioethical principles used in medical research trials, and bioethical concepts for space exploration should ultimately have the same goal: to minimize suffering and to maximize human safety.

In a work foundational to modern bioethics, Dr. Tom Beauchamp and Dr. James Childress identify four primary principles of bioethics: respect for autonomy,[64] non-maleficence,[65] beneficence,[66] and justice.[67] Their book, *Principles of Biomedical Ethics*, was published in 1979 and provides practical application for research involving human subjects. Applying these principles, in order to protect the autonomy of each space traveler, overseeing entities should make attempts to compile research that has already been conducted on the hazards of the space environment to properly inform participants of potential dangers Because knowledge of unknown dangers in space will be difficult to gather, communication of those hazards to space travelers will also be limited. As a result, individuals treading into new and unstudied territories may be limited in exercising their individual autonomy. In signing up for missions, for instance, uninformed individuals would not have the

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[64] TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 120, 128 (4th ed. 1994). Within medicine, for example, autonomy is considered to be respected through the informed consent of participants who are made aware of known risks and potential outcomes prior to taking part in a study. *See id.*

[65] *Id.* at 192. In a human subject context, Beauchamp and Childress define the principle of nonmaleficence as "[o]ne ought not to inflict evil or harm," while beneficence involves the principle that "[o]ne ought to prevent evil or harm . . . [o]ne ought to remove evil or harm . . . [and] [o]ne ought to do or promote good." *Id.*

[66] *Id.*

[67] *See generally id.* at 326. According to Beauchamp and Childress, equality is central to justice. *See id.*

ability choose or refuse to endure unreported hazards of the space environment.

The space environment also presents a paradox to notions of nonmaleficence and beneficence, as there are known and inherent dangers with exposing human beings to environments outside of Earth. Although the end goal of preserving the human race may eventually be beneficial to humankind, humans will be harmed as space societies are created. Related to preventing harm, maintaining equal access to outer space has been a promoted mission of some space-faring companies, including Virgin Galactic.[68] Upholding the principle of equal access, however, will be difficult as funding by large companies could lead to monopolization of the space industry and will inevitably prevent low-income and middle-class individuals globally from participating in initial missions. Building upon the broad overview of bioethical principles presented by Beauchamp and Childress, other laws and guidelines both within the United States and globally provide more practical applications of bioethics to human subject research that can provide insight into a framework for humans in space.

1. *A Universal Perspective: International Protections for Human Subjects*

Within medical experimentation, bioethical issues have transcended national borders. Global standards for regulating human studies and medical research have proliferated since the waning days of World War II. Of particular emphasis to this recent development are the United Nations Universal Declaration of Human Rights, the Nuremberg Code, and the Declaration of Helsinki.[69] Taken together, each of these declarations demonstrates that the international community has increasingly taken steps to expand protections for humans while simultaneously encouraging research, innovation, and advancement.

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[68] *Mission: What We Do*, VIRGIN GALACTIC, https://www.virgingalactic.com/mission/ (last visited Oct. 31, 2018). Virgin Galactic has a stated goal of "democratizing space." *See id.*

[69] *See infra* notes 70, 74, 77 and accompanying text.

In 1948, the United Nations ("UN") General Assembly set forth the Universal Declaration of Human Rights.[70] Although human health is not explicitly established as a human right within the Declaration, the articles of the proclamation do refer to the right to the "security of person"[71] and "the right to a standard of living adequate for the health and well-being of himself . . . [including] medical care."[72] Some have used the language of the Declaration to justify precautions within medical research.[73] With the onset of more humans living outside the bounds of Earth, declared human rights will inevitably extend to space travelers. The way in which these rights are protected, however, is still uncertain as maintaining a person's health in space will likely have greater barriers within the hostile space environment than on Earth.

One year after the UN's Declaration, in 1949, the Nuremberg trials prosecuting Nazi war criminals during the Holocaust initiated the creation of the Nuremberg Code to discourage illegal forms of medical experimentation.[74] The Code outlined several precautionary steps that should be taken when conducting human subject research. When translated into the space environment framework, four of these principles present significant complications in their application to human health in space:

> 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
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> 5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
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> 9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical

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[70] G.A. Res. 217A (III), Universal Declaration of Human Rights (Dec. 10, 1948).

[71] *Id.* at 3.

[72] *Id.* at 25(1).

[73] *See, e.g.*, Sabaratnam Arulkumaran, *Health and Human Rights*, 58 SING. MED. J. 4, 4–6 (2017).

[74] PERMISSIBLE MEDICAL EXPERIMENTS, in 2 *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, 181 (1949) (U.S. Gov't Printing Off.).

> or mental state, where continuation of the experiment seemed to him to be impossible.
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> 10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.[75]

Principles 4 and 5 denote avoidance of physical injury during medical trials, while Principles 9 and 10 present a concept of withdrawing from such research. In converting these medical experimentation doctrines to a bioethical framework for human space exploration, the very notion of sending humans into the hostile environment of outer space necessitates physical and mental suffering and injury. In addition, providing spacefarers with the autonomous liberty of deciding to end a trial, or even permitting the overseeing entity to terminate the mission during the course of the expedition, will be nearly impossible while humans are in space.

Utilizing the bioethical framework of the Nuremberg Code, space exploration and the resulting exposure of humans to the dangers of the space environment inherently stand in opposition to the human rights principles for the practice of human subject experimentation. If the goal is to protect human rights to the maximum extent by eliminating all risk, however, almost no medical experiment, clinical trial, or even routine procedure would be performed. Risk is inherent in any activity. Mitigation, though, should strive to avoid any "unnecessary" harm. Despite these observations, this principle still presents difficulties for exposure in space as facing any hazard may be considered necessary for survival.

Like the Nuremberg Code, the World Medical Association's Declaration of Helsinki, first established by its General Assembly in 1964, provides standards for human subject research conduct.[76] In the first paragraphs of the Declaration, the Assembly recognizes that

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[75] *Id.*

[76] *Declaration of Helsinki: Medical Research Involving Human Subjects*, WORLD MED. ASS'N (2018), https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/.

"[m]edical progress is based on research that ultimately must include studies involving human subjects."[77] Like the importance of human subjects to medical studies, humans in space, many would argue, are essential to the longevity of the human race.[78] Ultimately, however, as stated in the Declaration, the goal to generate new knowledge "can never take precedence over the rights and interests of individual research subjects."[79]

The Declaration recognizes the inherent risks and burdens of clinical trials but notes that "[m]edical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects."[80] Similarly, the Declaration makes exceptions for uncertainty in medical cases in which "proven interventions do not exist," allowing for risky research if the trial would offer "hope of saving life, re-establishing health or alleviating suffering."[81] Such exceptions may be used as "workaround" for supporters of humans in space, as the goal of eventually providing resources for future generations of humanity may be viewed as outweighing the present risks of exploration.

The Helsinki Declaration also notes the safety of human subjects is the duty of the physician[82] and that the physician should "'act in the patient's best interest.'"[83] In contrast to medical experimentation, no clear authority currently exists within space exploration to

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[77] WMA DECLARATION OF HELSINKI—ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS, WORLD MED. ASS'N ¶ 5 (2013), https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ [hereinafter WMA DECLARATION].

[78] *See* Kate Kelland, *Stephen Hawking Urges Space Mission to Save Humanity in 70th Birthday Address*, NAT'L POST (Jan. 9, 2012), http://news.nationalpost.com/2012/01/08/stephen-hawking-urges-be-curious-in-birthday-speech/.

[79] WMA DECLARATION, *supra* note 77, ¶ 8.

[80] *Id.* ¶ 16.

[81] *Id.* ¶ 37.

[82] *Id.* ¶ 4.

[83] *Id.* ¶ 3 (citing THE INTERNATIONAL CODE OF MEDICAL ETHICS, WORLD MED. ASS'N (1949), https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/.

assume the duty and responsibility for the health of space explorers. Additionally, the harm that occurs from the hazardous space environment will almost certainly not be in the individual's best interest. For service members in a Space Force, the authority may rest with the federal government, but space travelers on missions directed by commercial entities may be the responsibility of the overseeing corporations.

Providing for risk assessment, the Declaration of Helsinki, mandates that "careful assessment of predictable risks and burdens" must precede any research and that "[m]easures to [minimize] the risks must be implemented."[84] Additionally, evaluations of the trials must be performed "continually through research for their safety, effectiveness, efficiency, accessibility and quality."[85] Although some risks to human health in space have already been identified, the hazards will be difficult to measure due to the lack of a controlled environment.

Another concern with human space missions involves the high economic cost of such expeditions. Although the Declaration of Helsinki adds that "[g]roups that are underrepresented in medical research should be provided appropriate access to participation in research,"[86] the accessibility to life in outer space will likely be greatly impeded by a given individual's inability to pay for the cost of preparation, launch, operations, and potential return to Earth. Such barriers consequently limit the demographics of spacefarers to military members and billionaires, at least for the initial expansion of space exploration.[87]

Finally, participation in research must be voluntary and agreed to through informed consent.[88] This approach to informed consent will be foreseeably complex when addressing voluntary exposure in space as individuals will not have the opportunity to revoke consent or to end any harm due to the lengthened distance from Earth and

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[84] *Id.* ¶ 17.

[85] WMA DECLARATION, *supra* note 77, ¶ 6.

[86] *Id.* ¶ 13.

[87] Elon Musk, *First Lunar BFR Mission*, SPACEX, https://www.spacex.com/webcast (last visited Sept. 17, 2018) (introducing a Japanese billionaire as the first private citizen to orbit the moon).

[88] WMA DECLARATION, *supra* note 77, ¶ 25.

the lack of protection in the space environment. In particular, members of the proposed Space Force may also lack true informed consent while operating under military authority in space as exposure to hazards may be considered as simply part of the job. Like with current medical experimentation, precautions that respect autonomy, accessibility, and health will be essential components of providing protections of humans in space. Utilizing universal principles in the bioethics of medical experimentation can ultimately provide a framework for ensuring safety in space. Within human subject research on Earth, these international principles have also percolated into United States health policy and practice, ultimately contributing additional bioethical considerations for humans in space.

2. *Closer to Home: Protections for Human Subjects in the United States*

Although international policies provided an influx of bioethical standards following World War II, the United States put off addressing internal human subject violations for more than thirty years after the end of the war.[89] Adopted by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Belmont Report of 1979 became one of the first nationally-recognized declarations of human subject protection in the United States.[90] Similar to the bioethical framework

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[89] *See, e.g.*, *U.S. Public Health Service Syphilis Study at Tuskegee: Research Implications*, CDC, https://www.cdc.gov/tuskegee/after.htm (last reviewed Dec. 14, 2015) (observing that the Tuskegee Study changed the course of human subject research in the United States, leading to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974.)*; see also U.S. Public Health Service Syphilis Study at Tuskegee: Timeline*, CDC, https://www.cdc.gov/tuskegee/timeline.htm (last reviewed Dec. 22, 2015) (noting the injustices of the Tuskegee Study conducted by the Public Health Service between 1932 and 1974) ("The study involved 600 black men—399 with syphilis, 201 who did not have the disease. The study was conducted without the benefit of the patients' informed consent. Researchers told the men they were being treated for 'bad blood,' a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness.").

[90] *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T OF HEALTH & HUM. SERV'S., https://www.hhs.gov/ohrp/regulations-and-

of Beauchamp and Childress, in the Belmont Report, the Commission identified respect for persons, beneficence, and justice as core principles within human research.[91] The Report additionally proposed application of these principles through concepts of informed consent (including information, comprehension, and voluntariness), assessment of risks and benefits, and selection of subjects.[92] In applying the Belmont Report's principles to the future of humans in space, risks and hazards will be difficult to research in the space environment and as a result, participants in space missions will likely not be fully informed prior to launch. Advantages and disadvantages will also be placed on participants and those hoping to participate, as only a few individuals will likely have the opportunity to enter space during initial Space Force or commercial missions due to tight funding and restricted launching capabilities.

Current policy by the United States Department of Health and Human Services (HHS) on human subject research, also known as the "Common Rule," is expounded in 45 C.F.R. § 46.[93] Under 45 C.F.R. § 46.102, HHS policy requires the use of institutional research boards (IRBs) prior to human subject research.[94] IRBs, which are composed of five individuals from diverse backgrounds,[95] have the authority to review and approve or disapprove research proposals involving human beings.[96] As part of this authority, IRBs, can suspend or terminate approval of research that is not being conducted according to requirements or that is resulting in unexpected serious harm to subjects.[97] Translating this practice into exposing humans to the hazardous environment of outer space, an

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policy/regulations/common-rule/index.html (last reviewed Mar. 18, 2016) [hereinafter *Fed. Pol'y ('Common Rule')*].

[91] The Belmont Report—Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. 23,192 (Apr. 18, 1979); *see Fed. Pol'y ('Common Rule')*, *supra* note 90.

[92] The Belmont Report, at 44 Fed. Reg. 23,192; *see Fed. Pol'y ('Common Rule')*, *supra* note 90.

[93] *Fed. Pol'y ('Common Rule')*, *supra* note 90.

[94] Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. §§ 46.102(g)–(h) (2017).

[95] *Id.* § 46.107.

[96] *Id.* § 46.102(h).

[97] *Id.* § 46.113.

IRB will not have the opportunity to simply revoke a mission midway if unexpected serious harm to individuals occurs. This increases the dangers associated with space exploration in comparison to those experienced through clinical trials, supporting the need for even greater protections for humans in space travel.

Within the codified HHS policy, research investigators are required to obtain the informed consent of individuals before involving a human subject in research.[98] As part of this requirement, "information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information" must be provided.[99] With regard to space exploration, until space traveling becomes more widespread, a "reasonable [space] person" standard will likely not emerge.

Additionally, under HHS policy, the basic elements of informed consent also include a "description of any foreseeable risks or discomforts to the subject[,]"[100] an explanation of the "research subjects' rights, and whom to contact in the event of a research-related injury to the subject[,]"[101] and notice that "the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled[.]"[102] Similarly, researchers should disclose the "consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject[,]"[103] a statement that the subject's biospecimens "may be used for commercial profit and whether the subject will or will not share in this commercial profit[,]"[104] and whether research results will be provided to subjects.[105]

Informed consent, however, may be difficult to achieve when many risks are not known. For example, the risks of space travel will

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[98] *Id.* § 46.116(a)(1).
[99] *Id.* § 46.116(a)(4).
[100] *Id.* § 46.116(b)(2).
[101] *Id.* § 46.116(b)(7).
[102] *Id.* § 46.116(b)(8).
[103] *Id.* § 46.116(c)(4).
[104] *Id.* § 46.116(c)(7).
[105] *Id.* § 46.116(c)(8).

not be entirely known prior to launch and participants will not have the option to terminate the mission at any time. Some may argue that space travel cannot encompass informed consent at all due to the magnitude of unknown risks in space and the consequent lack of information to provide to participants. In addition, though HHS specifically notes that researchers must notify participants if biospecimens collected during studies will be used commercially, if space travelers join a mission under the authority of a company, there may be justification other than sample collection for gaining commercial profit from the travel as spacefarers will face extreme hardships in order to forge increased human presence in space.

Under HHS policy, researchers also may waive the informed consent requirement in particular cases, including if the "research involves no more than minimal risk to the subjects[,]"[106] the "research could not practicably be carried out without the requested waiver or alteration[,]"[107] or the "waiver or alteration will not adversely affect the rights and welfare of the subjects[.]"[108] Though "minimal risk" will likely be an understatement for the hazards humans face in space that may affect their welfare, governmental agencies and space corporations may attempt to waive informed consent requirements by arguing that a waiver of informed consent is practicable. In particular, for members of the Space Force, military regulations may ultimately increase the opportunity for such waivers in certain circumstances. In many cases, however, a lack of informed consent may serve as a basis for liability in the event of injury in space, as evidenced through human subject lawsuits within medical experimentation.

C. *Liability in the Lab: Precedent for Compensating Injury in Medical Research*

Liability within clinical trials is a growing area within United States and international court systems. Precedent for cases of human experimentation has expanded the traditional principles of bioethics into concrete mechanisms for recovery from injuries obtained

[106] *Id.* § 46.116(f)(3)(i).
[107] *Id.* § 46.116(f)(3)(ii).
[108] *Id.* § 46.116(f)(3)(iv).

during human subject research, both within the military and involving private individuals and companies. These cases may serve as an initial step toward evaluating the liability of injury to the human body in outer space. In the United States, avenues for legal liability differ between cases involving military members and those concerning private citizens. Many of these American law cases, however, are primarily founded on universal bioethical and accountability principles and, consequently, can easily translate beyond United States borders.

1. *The Force Be with You: Health Risk Liability for Military Members*

As demonstrated through international guidelines of bioethical treatment of human subjects, the notion of informed consent is an essential component to recognizing the importance of human autonomy. For military members under 21 C.F.R. § 50.23, however, the United States Food and Drug Administration's (FDA) informed consent requirement may be waived, allowing the Department of Defense ("DOD") to use military personnel as human subjects without consent.[109] In order to perform studies without consent, a determination must be made prior to experimentation that obtaining informed consent is not feasible and an IRB has approved of the tests being performed without informed consent.[110]

According to the DOD:

> There are times when the Department of Defense may obtain a waiver of the informed consent requirement from the [S]ecretary of [D]efense, which means that your informed consent will not be sought or obtained. This may occur for a number of reasons, such as emergency research or if the research study will advance the development of a medical product that is needed by the armed forces.[111]

This statute provides broad authority for the DOD to experiment upon service members, like those in the Space Force, requiring them

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[109] 21 C.F.R. § 50.23 (2017).

[110] *See id.*

[111] AM. HEALTH LAW. ASS'N, INFORMED CONSENT IN MILITARY MEDICAL RESEARCH: A GUIDE FOR MILITARY SERVICE MEMBERS 2 (2016), https://download.militaryonesource.mil/12038/MOS/AHLA/Informed_Consent_in_Military_Medical_Research.pdf.

to endure the detrimental effects of foreign environments, such as outer space, without knowledge of the consequences.

In a guide for service members, however, the DOD assures personnel that "[n]o military member may be forced to participate in any Department of Defense-funded or conducted medical research study."[112] Just as the language of 21 C.F.R. § 50.23 and DOD policies create quandaries for military members on earth, so too would they present similar difficulties for military members sent to space. Some may argue that military members will assume the risks of space just as service members in combat anticipate dangers in warzones. This notion, however, should not prevent military decision makers from taking proactive steps to protect service members, and to also provide mitigating compensation in the event of injury.

These service members are not, however, without recourse. The Department of Veterans Affairs ("VA") does provide avenues for past military members to receive compensation for disabilities resulting from specific environmental hazards such as particulate matter and certain pollutants.[113] The VA additionally grants compensation to members exposed to radiation.[114] Similarly, in the Agent Orange Act of 1991, Congress established a presumption of injury to service members from the Vietnam and Korean Wars who were exposed to chemical herbicides, enabling an easier process for obtaining compensation for certain disabilities.[115] In the future, if exposure to the space environment involves similar tragedies to those experienced in the Vietnam War, the Agent Orange Act may

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[112] *Id.*

[113] *Specific Environmental Hazards*, U.S. DEP'T OF VETERANS AFF., https://www.benefits.va.gov/COMPENSATION/claims-postservice-exposures-environmental_hazards.asp (last visited Dec. 20, 2018); *see* 38 C.F.R. § 3 (2017).

[114] *Post-Service Diseases Related to Exposure to Ionizing Radiation*, U.S. DEP'T OF VETERANS AFF., https://www.benefits.va.gov/COMPENSATION/claims-postservice-exposures-ionizing_radiation.asp (last visited Dec. 20, 2018); *see* 38 C.F.R. § 3.311 (2017); *see Radiogenic Diseases Post-Service*, U.S. DEP'T OF VETERANS AFF., https://www.benefits.va.gov/COMPENSATION/claims-postservice-exposures-radiogenic_diseases.asp (last visited Dec. 20, 2018).

[115] 38 U.S.C. § 101 (2017); *see Veterans Exposed to Agent Orange*, U.S. DEP'T OF VETERANS AFF., https://www.benefits.va.gov/compensation/claims-postservice-agent_orange.asp (last visited Dec. 20, 2018).

provide precedent for retroactively mitigating any harmful effects. In the alternative, these past experiences should additionally prompt governments to take proactive steps to protect service members from similar dangers.

There are many barriers, however, to lawsuits by military members against the United States for injuries. Although the Federal Tort Claims Act (FTCA) waives the sovereign immunity of the United States, plaintiffs can only sue the United States under certain narrow circumstances.[116] Under the *Feres* doctrine, "the Government is not liable under the Federal Tort Claims Act for injuries to servicemen where the injuries arise out of or are in the course of activity incident to service."[117] To simplify this doctrine, the Ninth Circuit outlined four factors a court should consider in determining whether a particular suit should be barred by the *Feres* doctrine:

> 1) the place where the negligent act occurred;
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> 2) the duty status of the plaintiff when the negligent act occurred;
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> 3) the benefits accruing to the plaintiff because of his status as a service member; and
>
> 4) the nature of the plaintiff's activities at the time the negligent act occurred.[118]

In evaluating these four factors, the Court should assess the "totality of the circumstances" in deciding if a suit is barred by the *Feres* doctrine.[119] Because of the nature of military service, the *Feres* doctrine creates a large barrier for service members seeking recovery from injuries. In contrast, for astronauts involved in past accidents, the federal government has generally paid out settlements

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[116] 28 U.S.C. § 1346(b) (2013).

[117] Feres v. United States, 340 U.S. 135, 146 (1950); *see id.* at 137, 146 (holding that an active duty service member who died in a fire in the barracks of a military camp cannot recover under the FTCA for alleged injuries by the negligence of the United States government); *see* Patricia Kime, *Tragedy and Injustice: The Heartbreaking Truth about Military Medical Malpractice*, MIL. TIMES (July 10, 2016), https://www.militarytimes.com/pay-benefits/military-benefits/health-care/2016/07/10/tragedy-and-injustice-the-heartbreaking-truth-about-military-medical-malpractice/ (noting that the *Feres* doctrine has garnered much debate about its unfairness to military members).

[118] Costo v. United States, 248 F.3d 863, 867 (9th Cir. 2001) (citation omitted).

[119] Dreier v. United States, 106 F.3d 844, 852 (9th Cir. 1996).

to the families of lost crewmembers, as in the 1986 *Challenger* and 2003 *Columbia* space shuttle disasters.[120]

Further, specific cases in which military members have undergone medical experimentation led by the military itself have established additional barriers to recovery. In *United States v. Stanley*,[121] for example, the United States Army experimented on service members using lysergic acid diethylamide (LSD).[122] One service member, James B. Stanley, volunteered to participate in a program deemed only "to test the effectiveness of protective clothing and equipment as defenses against chemical warfare[.]" In reality, he was subjected to secret administrations of LSD.[123]

From these doses, Stanley suffered from hallucinations, incoherence, memory loss, impaired performance, sleep deprivation, and violence against his wife and children.[124] Years later, Stanley filed suit against the United States on a claim of negligence under the FTCA.[125] Because Stanley's injury was incident to military service, under the *Feres* doctrine, he was not entitled to compensation for his injury.[126]

Similarly, in *Jaffee v. United States*,[127] United States Army commanding officers ordered Stanley Jaffee and other active soldiers to stand in a field without protection against radiation while

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[120] *See* Adam Liptak, *Loss of the Shuttle: The Courts; No Legal Precedent Is Seen Should Columbia Families Choose to Sue*, N.Y. TIMES (Feb. 6, 2003), https://www.nytimes.com/2003/02/06/us/loss-shuttle-courts-no-legal-precedent-seen-should-columbia-families-choose-sue.html (noting the millions of dollars in settlements from the government and a manufacturing company paid out to the *Challenger* victims' families); *see also $26.6 Million Paid to Columbia Families*, NBC NEWS (Apr. 16, 2007), http://www.nbcnews.com/id/18136153/ns/technology_and_science-space/t/million-paid-columbia-families/#.W53j5C2ZNR0 (describing the millions of dollars provided to families of the astronauts involved in the Columbia disaster).

[121] United States v. Stanley, 483 U.S. 669 (1987).

[122] *Id.* at 671.

[123] *Id.*

[124] *Id.*

[125] *Id.* at 672.

[126] *Id.*

[127] Jaffee v. United States, 663 F.2d 1226 (3d Cir. 1981).

a nuclear device was detonated nearby.[128] Jaffee claimed that as a result of this accident, he later developed cancer.[129] Although two dissenting judges from the Third Circuit acknowledged the severity of the actions in this case (in light of the Universal Declaration of Human Rights, the Nuremberg Code, and other standards of human subject research),[130] the majority ultimately did not allow for recovery under the *Feres* doctrine.[131]

The United States Supreme Court additionally discussed the reasons for barring lawsuits for service injuries, stating that such suits have an "effect on the willingness of military personnel to follow directions of their superiors."[132] The Court noted that "[s]crutinizing military decisions in civilian courts would 'involve second-guessing military orders, and would often require members of the Armed Services to testify in court as to each other's decisions and actions.'"[133] Such reasoning will likely be applied to military operations completed by the Space Force, leaving service members in space without recovery against the United States government if injuries occur in the hazardous environment of outer space. Since the *Feres* doctrine does not apply to private individuals,[134] however, other mechanisms for liability for injuries to private space travelers must be established.

2. *The Local Clinic: Health Risk Liability for Private Citizens and Non-U.S. Persons*

While the development of the Space Force may increase the number of military members exposed to hazardous environments, commercial enterprise in space will inevitably impact private citizens participating in space tourism and other exploration. Comparing the uncertainties of both human subject research and space exploration, liability suits brought by private citizens against government and corporate entities for medical experimentation can

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[128] *Id.* at 1229.
[129] *Id.*
[130] *Id.* at 1249.
[131] *Id.* at 1231.
[132] *Id.* at 1232.
[133] *Id.* at 1232 (citing Stencel Aero Eng'g Corp. v. United States, 431 U.S. 666, 673 (1977)).
[134] Feres v. United States, 340 U.S. 135, 146 (1950).

aid in framing standards for evaluating liability for injuries to private individuals in space. Although medical experimentation and research have been performed for centuries, advances in laboratory science and the absence of strong therapeutics following World War II demanded an increase in "well-controlled" studies.[135] The subsequent 1962 Kefauver-Harris Drug Amendments and the 1963 investigational drug regulations instituted by the federal government provide the FDA with the authority to regulate medical experimentation through clinical trials.[136] With smaller amounts of government funding for clinical drug trials, large pharmaceutical companies have gained greater control over medical testing.[137]

Corporation-driven research does have downsides, however, and many of these begin with money. Business venture and corporate greed have infiltrated healthcare and pharmaceuticals.[138] A lingering question for space enthusiasts is whether the influence of money upon the future of space exploration will cost too much, negatively impacting notions of peaceful discovery through property disputes, security threats, and even gambling with human health. Within space exploration, commercialization[139] is already occurring through public-private partnerships.[140] As a result, liability for injury in space may ultimately result in legal actions against both governmental entities and against private companies.

Although uncertainty currently exists with regard to health risks in space, through an evaluation of recovery for injuries in clinical trials and medical experimentation at-large, an attempt toward the

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[135] *See* SUZANNE WHITE JUNOD, U.S. FOOD & DRUG ADMIN., FDA AND CLINICAL DRUG TRIALS: A SHORT HISTORY 2 (2016), https://www.fda.gov/downloads/AboutFDA/History/ProductRegulation/UCM593494.pdf.

[136] *Id.* at 10.

[137] Michelle Llamas, *Big Pharma's Role in Clinical Trials*, DRUGWATCH (Apr. 19, 2018), https://www.drugwatch.com/featured/clinical-trials-and-hidden-data/.

[138] Carl Elliott, *Relationships between Physicians and Pharma: Why Physicians Should Not Accept Money from the Pharmaceutical Industry*, 4 NEUROLOGY CLINICAL PRAC. 164, 164–67 (2014).

[139] 51 U.S.C. § 50111 (2017).

[140] *See*, *e.g.*, Madison Tuttle, *NASA, Commercial Partners Progress to Human Spaceflight Home Stretch*, NASA, (July 27, 2018) https://www.nasa.gov/feature/nasa-commercial-partners-progress-to-human-spaceflight-home-stretch.

beginnings of a framework to evaluate liability in space can be established. Lawsuits brought by private citizens against both government and private corporations have developed a landscape for liability for medical experimentation. For example, in *Begay v. United States*,[141] Navajo uranium miners and their families brought suit against the federal government pursuant to the FTCA.[142] Prior to the conception of the case, in 1949, the state of Colorado and the Public Health Service (PHS) began a medical–environmental survey on the health dangers of uranium mining, by determining the "relationship between exposures to radioactivity and the biologic effect on miners" in order to develop methods to minimize exposure.[143] The plaintiffs alleged that the miners contracted lung cancer and other diseases from radiation exposure as a result of negligence by federal and state agencies who did not warn miners of the hazards involved with uranium mining.[144]

The district court found that the PHS physicians were only involved in the examination and its results and that such conduct was "consistent with the medical, ethical and legal standards of the 1940's and 1950's."[145] Despite a finding in 1959 that the results from the PHS study indicated a statistical increase above the number of expected deaths from lung cancer among miners, and suggestions being made to the Surgeon General that a federal response should be taken, the miners were not warned of any dangers.[146]

The Ninth Circuit ultimately affirmed the district court's dismissal of the case for lack of jurisdiction based upon the "discretionary function" exception under the FTCA,[147] which releases the United States government of liability in certain tort

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[141] Begay v. United States, 768 F.2d 1059 (9th Cir. 1985).

[142] *Id.* at 1060.

[143] *Id.* at 1060–61.

[144] *Id*. at 1060. During the study, the PHS gave miners who volunteered annual, then triennial, physical examinations. If a miner's test results were abnormal, the participant was referred to local medical facilities for treatment or further study. The PHS study team, however, "did not represent that it would provide health care to the members of the cohort." *Id.* at 1061.

[145] *Id.* at 1061–62.

[146] *Id.* at 1062.

[147] *Id.* at 1066.

actions. This exception excludes an act or omission by a federal employee that is:

> in the execution of a statute or regulation . . . or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.[148]

The Court determined that despite the fact that PHS suspected that the miners would suffer injury from the radiation, ultimately "the goal of the study was to determine the extent of the hazards so that recommendations could be made and standards promulgated."[149] As a result, the "type of decision, one not to warn, was clearly the type of decision of an agency which Congress sought to protect from judicial review under the Tort Claims Act."[150]

The liability suit pursued in the *Begay* case shares multiple parallels with future liability questions posed by human health risks in outer space. The miners in the *Begay* study were not intentionally exposed to radiation by the federal government. The nature of the uranium environment in which the miners worked inherently contained hazards to human health. Similarly, when more humans become exposed to the space environment, though a government agency or private company may not be forcing experimentation on space travelers, such individuals will nevertheless have exposure to certain hazards.

In the *Begay* case, though the government knew of these dangers and did not inform the miners, the government was still not liable for injuries associated with the hazards because (1) the federal

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[148] 28 U.S.C. § 2680(a).

[149] *Begay*, 768 F.2d at 1066.

[150] *Id.* Less than three years after the *Begay* case was decided, the U.S. Supreme Court established a two-part test for determining whether an action or omission falls under the discretionary exception. First, conduct is discretionary if it "involves an element of judgment or choice." Berkovitz v. United States, 486 U.S. 531, 536 (1988). Second, conduct is discretionary if it is a legislative or administrative decision "grounded in social, economic, and political policy." *Id.* at 536–37 (quoting United States v. S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines), 467 U.S. 797, 814 (1984)). This second component relates to protecting "Congress' desire to 'prevent judicial "second-guessing" of legislative and administrative decisions . . . through the medium of an action in tort.'" *Berkovitz*, 486 U.S. at 536–37 (quoting *Varig Airlines*, 467 U.S. at 814 (1984)).

employee(s) made a discretionary choice not to inform the workers, and (2) the choice involved a policy decision.[151] With such precedent, it seems that any combination of a decision backed up by a policy could justify the United States government in not warning individuals of known dangers. As a result, under a *Begay* framework, many people may sign up for a trip to space without knowing the dangers and ultimately will have difficulty in recovering for any injuries they endure from the space environment. If governments did inform individuals of known risks, on the other hand, the tort concept of assumption of the risk may serve as a mitigation factor also in favor of the government.

As space becomes more commercialized and companies begin to facilitate private transit in space, liability for injury in space will extend beyond governmental entities and into the private sector. With no current precedent in the space environment, liability for injury of human research subjects in clinical trials can provide insight into a possible model for liabilities in space. *Abdullahi v. Pfizer, Inc.*,[152] for example, involved a tort claim brought by non-U.S citizens against a United States pharmaceutical company for misconduct performed outside of the United States.[153] and provides a working parallel to injuries that may occur in non-United States territory in outer space.[154] In the wake of a bacterial meningitis epidemic in Nigeria, Pfizer collaborated with local physicians to test its new drug, Trovan. Two hundred sick Nigerian children were involved in the experiment—half receiving Tovan, the other half, a well-established drug.[155]

Prior to the trial, Pfizer allegedly did not disclose the serious risks involved with the study and failed to obtain informed consent from the children or their guardians.[156] Pfizer additionally did not notify the subjects or their guardians about side effects, did not notify them of options to choose alternative treatment, and did not inform them that another organization was offering a conventional,

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[151] *See Berkovitz*, 486 U.S. at 536–37.
[152] Abdullahi v. Pfizer, Inc., 562 F.3d 163 (2d Cir. 2009).
[153] *Id.* at 169.
[154] *Id.*
[155] *Id.*
[156] *Id.*

effective treatment for bacterial meningitis at the same site as the Pfizer study.[157] As a result of the trial, the experiments allegedly caused the deaths of eleven children, and left many others blind, deaf, paralyzed, or brain-damaged.[158]

The Second Circuit ultimately analyzed the case under the Alien Tort Statute.[159] In the analysis, the Court noted that conduct violating the law of nations that is of mutual, universal concern is actionable under the Act.[160] Additionally, private actors can be held liable under the Alien Tort Statute if acting in concert with a State.[161] In analyzing the Pfizer case under the Alien Tort Statute, the Court cited the Nuremberg Code and the Universal Declaration of Human Rights as international proclamations against uninformed consent in human experimentation.[162] Pfizer eventually settled the case with the Nigerian state of Kano for $75 million.[163]

By comparing misconduct by private companies initiating medical experimentation on Earth to the risks to human health that individuals will face on commercial missions in space, the *Abdullahi* case raises potential methods for dealing with future space liabilities. As the incidents in the case occurred on non-United States soil, international law played a significant role in the *Abdullahi* Court's decision under the Alien Tort Statute. As the space environment, whether on another celestial body or within the vacuum of space itself, would likely be considered non-United States territory,[164] the Alien Tort Statute and its incorporation of

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[157] *Id.* at 170.

[158] *Id.* at 169.

[159] 28 U.S.C. § 1350 (2017) ("The district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States.").

[160] *Abdullahi*, 562 F.3d at 172–73.

[161] *Id.* at 188 (citing Kadic v. Karadzic, 70 F.3d 232, 245 (2d Cir. 1995)).

[162] *Id.* at 176.

[163] *Federal Statutes — Alien Tort Statute — Second Circuit Looks Beyond Complaint to Find State Action Requirement Satisfied. —* Abdullahi v. Pfizer, Inc., *562 F.3d 163 (2d Cir. 2009)*, 123 HARV. L. REV. 768, 775 n.69 (2010).

[164] *See* Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies, Dec. 19, 1966, 610 U.N.T.S. 205, at art. II (stating that "[o]uter space, including the moon and other celestial bodies, is not subject to national

universality of international law may play a larger role in liability disputes beyond Earth in the context of actions by American companies.

In the *Abdullahi* case, the lack of communication by Pfizer concerning informed consent, risks, and alternative options ultimately led the Court to consider the pharmaceutical company's actions as violating mutual international law.[165] This reasoning can be translated to attempts by travelers to recover from injuries sustained through commercially-sponsored space travel. For instance, if companies do not follow internationally recognized concepts of informed consent and communication of risks, they may be held liable under the Alien Tort Statute or similar law. In particular, the Alien Tort Statue may be even more applicable when private space companies partner with government on space missions, as these entities may not be bound by national boundaries.[166] Ultimately, as in the *Abdullahi* case, the Nuremberg Code, the Universal Declaration of Human Rights, and other bioethical standards[167] will likely extend beyond the bounds of Earth into the liability of health risks in space.

IV. READY FOR LAUNCH: PROPOSED FRAMEWORK

Because space colonization has not yet occurred, many questions remain unanswered. In applying universal bioethical principles to the future of humans in space, risks and hazards should be extensively researched prior to sending humans into space in order to inform the participants with as much information as possible. Additionally, selection of subjects should ensure unfair advantages or disadvantages are not imposed on potential participants. Policies must ultimately be established in advance of the establishment of a colony in order to preserve the integrity of space and of the human race itself.

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appropriation by claim of sovereignty, by means of use or occupation, or by any other means.").

[165] *Abdullahi*, 562 F.3d at 169–70, 172.

[166] *See id.* at 188 (citing *Kadic*, 70 F.3d at 245).

[167] *Id.* at 176.

Traditional bioethical principles of autonomy, beneficence, malfeasance, and justice must be foundational to a future for humans in space. From the UN's Universal Declaration of Humans Rights establishing a right to a standard of living that provides health and well-being,[168] to the Nuremberg Code's insistence upon avoiding unnecessary harm,[169] precautionary measures should be implemented by international and national agencies in order to ensure protection and safety for humans in space. This will involve balancing risks and as the World Medical Association suggests with regard to medical research, risky endeavors should only be "conducted if the importance of the objective outweighs the risks and burdens to the research subjects."[170] Similarly, further research on the hazards of space will be required in order for space organizations to impart the requisite knowledge necessary for space travelers to provide informed consent[171] in space endeavors. Scientific agencies should create further partnerships with private companies to better assess human health risks in space in order to minimize dangers as much as possible and to provide essential information to space travelers.

With regard to military service members who will be part of the United States Space Force, military authorities should also begin work to build upon current research in space. Providing service members with as much information as possible about the dangers of space missions will aid in protecting the individual autonomy of members. Additionally, liability schemes will likely develop from common law civil suits if the space environment results in unfortunate injuries to Space Force members. This liability will likely be based upon military case law precedent, including the *Feres* doctrine, limiting suits by military personnel against the United States.[172] This precedent under the FTCA,[173] however, should

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[168] *See* G.A. Res. 217A (III), Universal Declaration of Human Rights, at art. 25 (Dec. 10, 1948).

[169] *See supra* note 74; *supra* text accompanying note 75.

[170] *See* WMA DECLARATION, *supra* note 77, § 16.

[171] *See* 45 C.F.R. §§ 46.116(b)(2), (7) (2017); *supra* text accompanying notes 101–02.

[172] *See* Feres v. United States, 340 U.S. 135, 146 (1950).

[173] *See* 28 U.S.C. § 1346(b) (2013).

be reviewed by lawmakers seeking to apply its principles to space as inherent dangers, family separation, and lack of opportunity for withdrawal from space missions should weigh more heavily in favor of holding the government accountable for injuries in space.

Similarly, private individuals endeavoring into space through commercial means should also be provided with consideration for their autonomy, safety, and recovery in the event of injury. Currently, lawsuits against both governments and private companies within medical experimentation and clinical trials have had mixed success for injured plaintiffs. In negligence suits, for example, a lack of knowledge of risks in space on the part of the mission provider may result in no compensation to participants for harm caused by the space environment. Despite this precedent, without knowledge of risk, participants cannot truly provide informed consent and may venture blindly into the vast unknown of outer space lacking understanding of potential dangers. Space entities overseeing these missions may, though, be held liable for not providing informed consent.[174] In the interest of protecting themselves, space companies should foster partnerships with government space and medical agencies to better research the risks to human health in space. Such practice will have a positive impact on both the safety and well-being of humans in space, as well as on the economic development cultivated by the commercialization of space.

Further scientific research is imperative to ensuring the welfare of humans in space. Ultimately, however, bioethical principles are universal. The similarities between the unknown risks of current medical experimentation and the uncertain hazards in the space environment can inform researchers and lawmakers alike of a framework for legal precautions and liability for human health in space. Using this framework as a foundation, policies must precede the potential influx of humans in space through the Space Force and the commercialization of space travel and colonization. As humans look to a future in space, "one small step for man, one giant leap for mankind"[175] toward widespread human settlement in space just may

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[174] *See* Abdullahi v. Pfizer, Inc., 562 F.3d 163, 176 (2d Cir. 2009).
[175] *July 20, 1969: One Giant Leap for Mankind*, NASA (July 20, 2017), https://www.nasa.gov/mission_pages/apollo/apollo11.html.

be a leap in the wrong direction if the issues surrounding bioethics in outer space are not resolved.